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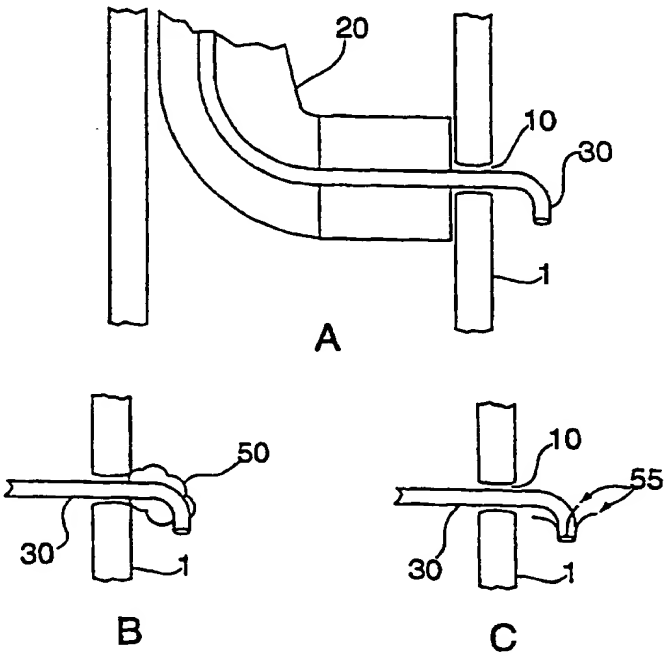
(54) Title: VESSEL CUTTING DEVICES

(57) Abstract

A catheter-based system for accessing specific body cavities percutaneously and minimizing patient trauma is provided. In the preferred embodiment, in order to create an aperture at an access site in a patient's existing tubular body organ structure, a delivery sheath is passed axially along the interior of a portion of the existing tubular body organ structure to place a distal end of the delivery sheath near the access site. A centering wire is passed axially along the interior of the delivery sheath, piercing through from inside to outside of the patient's existing tubular body organ structure at the access site by causing an end portion of the centering wire to emerge from the distal end of the delivery sheath. A cutting catheter is passed substantially coaxially over the centering wire and axially along the interior of the delivery sheath. The aperture is formed by advancing a distal end of the cutting catheter through from inside to outside of the patient's existing tubular body organ structure at the access site and advancing the distal end of the delivery sheath through from inside to outside of the patient's existing tubular body organ structure at the access site.



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# VESSEL CUTTING DEVICES

## Background of the Invention

This invention relates to vessel cutting devices for use in the repair, replacement or supplement of a medical patient's natural body organ structures or tissues. More particularly, this invention relates to vessel cutting devices for use in vascular anastomosis (the surgical connection of vessels).

An example of the possible uses of the invention is a minimally invasive cardiac bypass procedure. This and other examples are considered in detail in Goldsteen et al., U.S. Patent Application No. 08/745,618, filed November 7, 1996, which is hereby incorporated by reference herein in its entirety.

Vascular anastomosis is a delicate and time-consuming procedure in which fast and accurate vessel cutting plays a particularly important role.

In view of the foregoing, it would be desirable to provide a catheter-based system for accessing specific body cavities percutaneously, thereby minimizing patient trauma.

It would also be desirable to provide fast and accurate vessel cutting devices.

Summary of the Invention

It is an object of the present invention to provide a catheter-based system for accessing specific body cavities percutaneously, thereby minimizing patient trauma. It is also an object to provide fast and accurate vessel cutting devices.

These and other objects are accomplished by providing a method and apparatus for creating an aperture at an access site in a patient's existing tubular body organ structure by passing a delivery sheath axially along the interior of a portion of the existing tubular body organ structure to place a distal end of the delivery sheath near the access site, passing a centering wire axially along the interior of the delivery sheath, piercing through from inside to outside of the patient's existing tubular body organ structure at the access site by causing an end portion of the centering wire to emerge from the distal end of the delivery sheath, passing a cutting catheter substantially coaxially over the centering wire and axially along the interior of the delivery sheath, forming the aperture by advancing a distal end of the cutting catheter through from inside to outside of the patient's existing tubular body organ structure at the access site and advancing the distal end of the delivery sheath through from inside to outside of the patient's existing tubular body organ structure at the access site.

In one embodiment, the distal end of the cutting catheter is rotated to cut through the patient's existing tubular body organ structure at the access site. In another embodiment, a cutting catheter with a conical (preferably star-shaped) cutting edge is

pushed through the patient's existing tubular body organ structure at the access site.

The present invention can also be used to create an aperture in the patient's existing tubular body organ structure by advancing a distal end of the cutting catheter through from outside to inside of the patient's existing tubular body organ structure at the access site.

In the most preferred embodiment, all or substantially all necessary apparatus is inserted into the patient via the patient's existing body organ vessel. In addition, all or substantially all apparatus functions are controlled by the physician (a term used herein to also include supporting technicians) from outside the patient's body.

Brief Description of the Drawings

The above and other objects and advantages of the invention will be apparent upon consideration of the following detailed description, taken in conjunction with the accompanying drawings, in which like reference characters refer to like parts throughout, and in which:

FIG. 1a is a simplified sectional view showing the distal end of a delivery sheath in the interior of a portion of the existing tubular body organ structure with a centering wire piercing through from inside to outside of the patient's existing tubular body organ structure at the access site;

FIG. 1b is a view similar to portions of FIG. 1a showing a centering wire piercing through from inside to outside of the patient's existing tubular body organ structure at the access site, wherein the

end portion of the centering wire includes a selectively enlargeable structure;

FIG. 1c is another view similar to portions of FIG. 1a showing a centering wire piercing through from inside to outside of the patient's existing tubular body organ structure at the access site, wherein the end portion of the centering wire includes fasteners;

FIG. 2 is yet another view similar to FIG. 1a showing a cutting catheter positioned for cutting at the distal end of a delivery sheath at the access site;

FIG. 3 is still another view similar to FIG. 1a showing forming the aperture by advancing a distal end of the cutting catheter through from inside to outside of the patient's existing tubular body organ structure at the access site;

FIG. 4 is yet another view similar to FIG. 1a showing advancing the distal end of the delivery sheath through from inside to outside of the patient's existing tubular body organ structure at the access site;

FIG. 5 is a simplified elevational view, partly in section, showing the distal end of the cutting catheter advancing through from outside to inside to create an aperture in the patient's existing tubular body organ structure;

FIG. 6 is a side view of the patient's existing tubular body organ structure of FIG. 5, showing the aperture created;

FIG. 7a is still another view similar to FIG. 1a showing the distal end of a delivery sheath in the interior of a portion of the existing tubular body organ structure with a centering wire piercing through from inside to outside of the patient's existing

tubular body organ structure at the access site, wherein the cutting catheter includes a dilator;

FIG. 7b is yet another view similar to FIG. 1a forming the aperture by advancing a distal end of the cutting catheter through from inside to outside of the patient's existing tubular body organ structure at the access site, wherein the cutting catheter includes a dilator;

FIG. 7c is still another view similar to FIG. 1a showing advancing the delivery sheath through the aperture at the access site; and

FIG. 8 is yet another view similar to FIG. 1a showing a delivery sheath which includes distal and proximal selectively enlargeable structures.

Detailed Description of the Invention

As a preliminary step in creating an aperture at an access site 10 in a patient's existing tubular body organ structure 1, a delivery sheath 20 is passed axially along the interior of a portion of tubular body organ structure 1 to place a distal end of delivery sheath 20 near access site 10. When the distal end of delivery sheath 20 is proximal to access site 10, a centering wire 30 is passed axially along the interior of the sheath until the end portion of centering wire 30 emerges from the distal end of the sheath and pokes through from inside to outside of tubular body organ structure 1. Centering wire 30 provides a pilot track for cutting catheter 40 to follow. FIG. 1a shows the distal end of delivery sheath 20 in the interior of a portion of tubular body organ structure 1 with a centering wire 30 piercing through from inside to outside of the organ structure at access site 10.

The distal end of centering wire 30 is preferably deformable to facilitate deployment and removal, but resumes its operational (preferably hooked) shape once deployed. Centering wire 30 is kept relatively straight when it is inside sheath 20. But, when centering wire 30 is pushed axially out the distal end of sheath 20, it curves to one side, as shown in FIGS. 1a, 1b and 1c. FIGS. 1b and 1c show alternative structures for centering wire 30. In FIG. 1b, the end portion of centering wire 30 includes a selectively enlargeable structure (such as a balloon 50 which extends annularly around the exterior of the centering wire and projects radially outwardly from the centering wire in all radially outward directions when inflated). In FIG. 1c, the end portion of centering wire 30 includes struts 55 spaced circumferentially around centering wire 30 and which are resiliently biased to project from the centering wire after the end portion of the centering wire pierces through body organ structure 1 at access site 10. By providing a selectively enlargeable structure disposed on the exterior of the centering wire at a predetermined distance proximally from the distal end of the centering wire and enlarging that structure after the centering wire has pierced organ structure 1, it is possible to prevent the portion of centering wire 30 which is distal of the enlargeable structure from passing back into the organ structure. In addition to the retaining function, the enlargeable structure serves to seal the aperture and displace tissue from around the outside of organ structure 1 near access site 10, thereby creating a space. Such a space helps to prevent cutting head 45 from cutting other tissues after exiting organ structure 1 at access site 10.

After piercing through organ structure 1 at access site 10 with centering wire 30, cutting catheter 40 is passed substantially coaxially over the centering wire and axially along the interior of sheath 20. FIG. 2 shows cutting head 45 of cutting catheter 40 positioned for cutting at the distal end of delivery sheath 20 at access site 10.

Centering wire 30 holds cutting catheter 40 and delivery sheath 20 against organ structure 1 at access site 10, thereby preventing undue bleeding during and after the creation of the aperture that could occur if the cutting catheter and the delivery sheath were to move away from the access site. FIG. 3 shows how the aperture is formed by advancing the distal end of cutting catheter 40 (i.e., cutting head 45) through from inside to outside of organ structure 1 at access site 10 by rotating and/or pushing the distal end of the cutting catheter.

As shown in FIGS. 2, 3, and 4, the distal end of cutting catheter 40 has a circular cutting edge. Cutting catheter 40, which when advanced by rotation, cuts through tissue and removes tissue plug 60. The preferred embodiment of cutting head 45 also includes a serrated cutting edge and an axially aligned recess for accepting tissue plug 60. By removing plug 60 of tissue (rather than merely displacing tissue, as in FIGS. 5 and 6), the elastic recoil of organ structure 1 at access site 10 is reduced, which may be a desirable condition for optimal graft attachment.

FIG. 4 shows advancing the distal end of delivery sheath 20 through from inside to outside of organ structure 1 at access site 10 and removing centering wire 30 and cutting catheter 40 along with tissue plug 60 contained within cutting head 45.

As shown in FIG. 5, non-rotating cutting catheter 40 can be used to create specific geometric aperture shapes (e.g., oblong aperture 70 for coronary anastomosis). FIG. 5 also shows the use of the present invention in creating an aperture organ structure 1 by advancing a distal end of cutting catheter 40 through from outside to inside of the organ structure at access site 10. Centering wire 30 is tracked through cutting catheter 40 and is shown piercing organ structure 1 at access site 10. Following such an outside-to-inside aperture, delivery sheath 20 can be passed axially along the interior of a portion of organ structure 1 to place a distal end of delivery sheath 20 near second access site 10 where an inside-to-outside aperture can be created. (Note that organ structure 1 is shown smaller in scale relative to sheath 20 and cutting catheter 40.)

FIG. 6 is a side view of organ structure 1, showing aperture 70 created using non-rotating cutting catheter 40 of FIG. 5.

Cutting catheter 40 shown in FIG. 7a is a rotating catheter. Cutting head 45 could be a saw-tooth or a razor-edge type, for example. The distal end of delivery sheath 20 is shown in the interior of a portion of organ structure 1 with centering wire 30 piercing through from inside to outside of the organ structure at access site 10, wherein cutting catheter 40 includes dilator 80. Dilator 80 facilitates advancing sheath 20 through the aperture (as is shown by the succession of steps illustrated by FIGS. 7b and 7c).

The outer diameter of dilator 80 is close to the inner diameter of sheath 20 and is typically larger than the diameter of cutting head 45. As shown in FIG.

7b, as dilator 80 advances through the aperture at access site 10, the aperture is simultaneously sealed against bleeding.

FIG. 8 shows delivery sheath 20 which includes proximal and distal selectively enlargeable structures 90, 100. Preferably, both selectively enlargeable structures 90, 100 are balloons which extend annularly around the exterior of delivery sheath 20 and project radially outward when inflated. Although the embodiment shown in FIG. 8 includes both proximal and distal selectively enlargeable structures, either one or both may be included. When enlarged, proximal selectively enlargeable structure 90 prevents more than the portion of delivery sheath 20 which is distal of the enlargeable structure from passing out of the tubular structure via the aperture. Similarly, when enlarged, distal selectively enlargeable structure 100 prevents the portion of delivery sheath 20 which is distal of the enlargeable structure from passing back in to the tubular structure via the aperture.

As an illustrative example of the application of the present invention, consider the following. Delivery sheath 20 (preferably about 4.0 mm in diameter) including cutting catheter 40 is introduced into organ structure 1 percutaneously through the femoral artery near the thigh. Cutting catheter 40 includes cutting head 45 (preferably about 3.5 mm in diameter). Delivery sheath 20 is positioned at access site 10, here the ascending aorta. Centering wire 30 is tracked through cutting catheter 40 and is caused to pierce the aortic artery at access site 10. Cutting catheter 40 is then tracked over centering wire 30 by either pushing or rotating (or a combination of both pushing and rotating) and caused to advance through the

aortic wall. An approximately 3.5 mm aperture is created with tissue plug 60 retained in cutting head 45 and removed along with the cutting catheter 40. Delivery sheath 20 can now be advanced through the approximately 3.5 mm aperture created by the cutting catheter 40, causing organ structure 1 to stretch slightly (i.e., about 0.5 mm). This stretching is desirable because it provides a blood seal around delivery sheath 20 to prevent bleeding into the chest cavity. Delivery sheath 20 can now be used to introduce other catheters (including cameras, for example) from the femoral artery into the chest cavity for the purpose of diagnosis or intervention (e.g., grafts or TMR laser surgery).

To minimize patient trauma, delivery sheath 20, cutting catheter 40 and centering wire 30 are all preferably coupled to and controlled by a controller located on the outside of the patient.

Various methods and apparatus for delivering and installing plugs in walls of organ structures, as well as methods and apparatus for promoting the closing and healing of apertures in walls of organ structures, are available (e.g., of the type shown in Goldsteen et al. U.S. patent application No. 08/745,618, filed November 7, 1996; Goldsteen et al. U.S. patent application No. 08/839,198, filed April 23, 1997; and Sullivan et al. U.S. patent application No. 08/869,808, filed June 5, 1997, all of which are hereby incorporated by reference herein).

Thus, it is seen that a method and apparatus for creating an aperture at an access site in a patient's existing tubular body organ structure and making it possible to access specific body cavities percutaneously, thereby minimizing patient trauma, is

provided. One skilled in the art will appreciate that the present invention can be practiced by other than the described embodiments, which are presented for purposes of illustration and not of limitation, and the present invention is limited only by the claims which follow.

What is claimed is:

1. An apparatus for creating an aperture at an access site in a patient's existing tubular body organ structure comprising:

a delivery sheath insertable axially along the interior of a portion of said existing tubular body organ structure;

a centering wire insertable axially along the interior of said delivery sheath and adapted for piercing through said patient's existing tubular body organ structure at said access site; and

a cutting catheter insertable substantially coaxially over said centering wire and axially along the interior of said delivery sheath, said cutting catheter including a distal end adapted for advancing through said patient's existing tubular body organ structure at said access site by rotation to form said aperture.

2. The apparatus of claim 1 wherein said distal end of said delivery sheath includes a first selectively enlargeable structure disposed on its exterior at a predetermined distance proximally from its distal end for selectively preventing more than the portion of said delivery sheath which is distal of said enlargeable structure from passing out of said tubular structure via said aperture by selectively enlarging said first selectively enlargeable structure.

3. The apparatus of claim 1 wherein said distal end of said delivery sheath includes a second selectively enlargeable structure disposed on its exterior at a predetermined distance proximally from

its distal end for selectively preventing the portion of said delivery sheath which is distal of said enlargeable structure from passing back into said tubular structure via said aperture by selectively enlarging said second selectively enlargeable structure.

4. The apparatus of any one of claims 2 through 3 wherein each of said first and second enlargeable structures comprises an inflatable balloon.

5. The apparatus of claim 1 wherein said distal end of said cutting catheter comprises a substantially circular cutting edge with an axially aligned recess for accepting a tissue plug generated during formation of said aperture.

6. The apparatus of claim 1 wherein said distal end of said cutting catheter comprises a substantially circular serrated cutting edge with an axially aligned recess for accepting a tissue plug generated during formation of said aperture.

7. The apparatus of claim 1 wherein the end portion of said center wire is deformable to facilitate deployment and removal, but resumes its operational shape once deployed.

8. The apparatus of claim 1 wherein the end portion of said centering wire includes struts mounted on said centering wire, said struts being resiliently biased to project from said center wire after the end portion of said centering wire pierces through from

inside to outside of said patient's existing tubular body organ structure at said access site.

9. The apparatus of claim 8 wherein said struts comprise:

a plurality of fingers spaced circumferentially around said centering wire, each of said fingers being resiliently biased to project from said centering wire.

10. The apparatus of claim 1 wherein the end portion of said centering wire includes a selectively enlargeable structure disposed on its exterior at a predetermined distance proximally from its distal end for selectively preventing the portion of said centering wire which is distal of said enlargeable structure from passing back into said tubular structure via said aperture by selectively enlarging said second selectively enlargeable structure.

11. The apparatus of claim 10 wherein said enlargeable structure comprises an inflatable balloon.

12. The apparatus of claim 1 wherein said cutting catheter further includes a dilator positioned substantially coaxially over said cutting catheter.

13. An apparatus for creating an aperture at an access site in a patient's existing tubular body organ structure comprising:

a delivery sheath insertable axially along the interior of a portion of said existing tubular body organ structure;

a centering wire insertable axially along the interior of said delivery sheath and adapted for piercing through said patient's existing tubular body organ structure at said access site; and

a cutting catheter insertable substantially coaxially over said centering wire and axially along the interior of said delivery sheath, said cutting catheter including a distal end including a conical cutting edge adapted for advancing through said patient's existing tubular body organ structure at said access site to form said aperture.

14. The apparatus of claim 13 wherein said distal end of said delivery sheath includes a first selectively enlargeable structure disposed on its exterior at a predetermined distance proximally from its distal end for selectively preventing more than the portion of said delivery sheath which is distal of said enlargeable structure from passing out of said tubular structure via said aperture by selectively enlarging said first selectively enlargeable structure.

15. The apparatus of claim 13 wherein said distal end of said delivery sheath includes a second selectively enlargeable structure disposed on its exterior at a predetermined distance proximally from its distal end for selectively preventing the portion of said delivery sheath which is distal of said enlargeable structure from passing back into said tubular structure via said aperture by selectively enlarging said second selectively enlargeable structure.

16. The apparatus of any one of claims 14 through 15 wherein each of said first and second enlargeable structures comprises an inflatable balloon.

17. The apparatus of claim 13 wherein the end portion of said center wire is deformable to facilitate deployment and removal, but resumes its operational shape once deployed.

18. The apparatus of claim 13 wherein the end portion of said centering wire includes struts mounted on said centering wire, said struts being resiliently biased to project from said center wire after the end portion of said centering wire pierces through from inside to outside of said patient's existing tubular body organ structure at said access site.

19. The apparatus of claim 18 wherein said struts comprise:

a plurality of fingers spaced circumferentially around said centering wire, each of said fingers being resiliently biased to project from said centering wire.

20. The apparatus of claim 14 wherein the end portion of said centering wire includes a selectively enlargeable structure disposed on its exterior at a predetermined distance proximally from its distal end for selectively preventing the portion of said centering wire which is distal of said enlargeable structure from passing back into said tubular structure via said aperture by selectively

enlarging said second selectively enlargeable structure.

21. The apparatus of claim 20 wherein said enlargeable structure comprises an inflatable balloon.

22. The apparatus of claim 14 wherein said cutting catheter further includes a dilator positioned substantially coaxially over said cutting catheter.

23. A method for creating an aperture at an access site in a patient's existing tubular body organ structure comprising the steps of:

passing a delivery sheath axially along the interior of a portion of said existing tubular body organ structure to place a distal end of said delivery sheath near said access site;

passing a centering wire axially along the interior of said delivery sheath;

piercing through from inside to outside of said patient's existing tubular body organ structure at said access site by causing an end portion of said centering wire to emerge from said distal end of said delivery sheath;

passing a cutting catheter substantially coaxially over said centering wire and axially along the interior of said delivery sheath;

forming said aperture by advancing a distal end of said cutting catheter through from inside to outside of said patient's existing tubular body organ structure at said access site by rotating said distal end; and

advancing said distal end of said delivery sheath through from inside to outside of said

patient's existing tubular body organ structure at said access site, thereby dilating said patient's existing tubular body organ structure at said access site and creating a fluid seal between said delivery sheath and said existing tubular body organ structure at said access site.

24. A method for creating an aperture at an access site in a patient's existing tubular body organ structure comprising the steps of:

passing a delivery sheath axially along the interior of a portion of said existing tubular body organ structure to place a distal end of said delivery sheath near said access site;

passing a centering wire axially along the interior of said delivery sheath;

piercing through from inside to outside of said patient's existing tubular body organ structure at said access site by causing an end portion of said centering wire to emerge from said distal end of said delivery sheath;

passing a cutting catheter substantially coaxially over said centering wire and axially along the interior of said delivery sheath, said cutting catheter including a distal end which comprises a conical cutting edge;

forming said aperture by advancing said distal end of said cutting catheter through from inside to outside of said patient's existing tubular body organ structure at said access site; and

advancing said distal end of said delivery sheath through from inside to outside of said patient's existing tubular body organ structure at said access site, thereby dilating said patient's existing

tubular body organ structure at said access site and creating a fluid seal between said delivery sheath and said existing tubular body organ structure at said access site.

25. A method for creating an aperture at an access site in a patient's existing tubular body organ structure comprising the steps of:

placing a distal end of a delivery sheath near said access site;

passing a centering wire axially along the interior of said delivery sheath;

piercing through from outside to inside of said patient's existing tubular body organ structure at said access site by causing an end portion of said centering wire to emerge from said distal end of said delivery sheath;

passing a cutting catheter substantially coaxially over said centering wire and axially along the interior of said delivery sheath;

forming said aperture by advancing a distal end of said cutting catheter through from outside to inside of said patient's existing tubular body organ structure at said access site by rotating said distal end; and

advancing said distal end of said delivery sheath through from outside to inside of said patient's existing tubular body organ structure at said access site, thereby dilating said patient's existing tubular body organ structure at said access site and creating a fluid seal between said delivery sheath and said existing tubular body organ structure at said access site.

26. A method for creating an aperture at an access site in a patient's existing tubular body organ structure comprising the steps of:

placing a distal end of a delivery sheath near said access site;

passing a centering wire axially along the interior of said delivery sheath;

piercing through from outside to inside of said patient's existing tubular body organ structure at said access site by causing an end portion of said centering wire to emerge from said distal end of said delivery sheath;

passing a cutting catheter substantially coaxially over said centering wire and axially along the interior of said delivery sheath, said cutting catheter including a distal end which comprises a conical cutting edge;

forming said aperture by advancing a distal end of said cutting catheter through from outside to inside of said patient's existing tubular body organ structure at said access site; and

advancing said distal end of said delivery sheath through from outside to inside of said patient's existing tubular body organ structure at said access site, thereby dilating said patient's existing tubular body organ structure at said access site and creating a fluid seal between said delivery sheath and said existing tubular body organ structure at said access site.

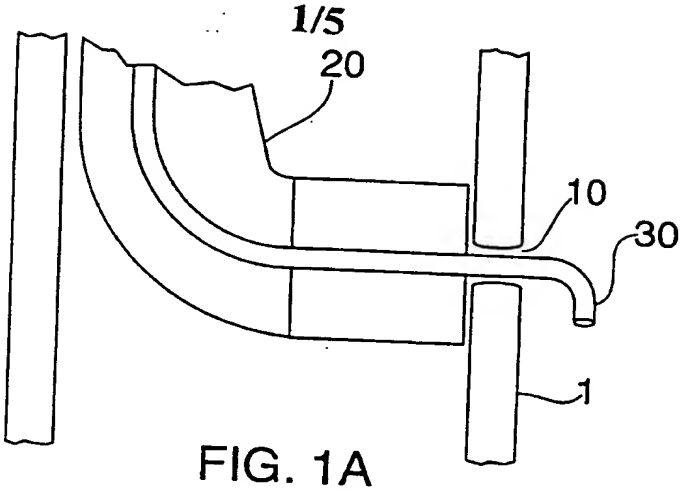


FIG. 1A

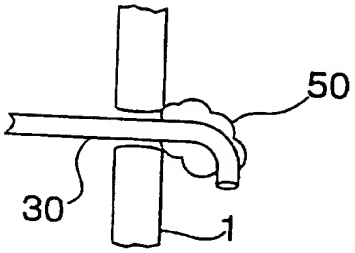


FIG. 1B

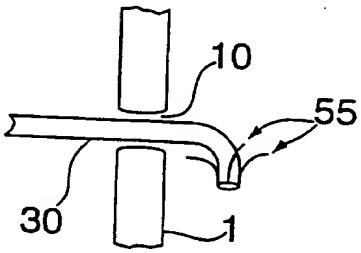


FIG. 1C

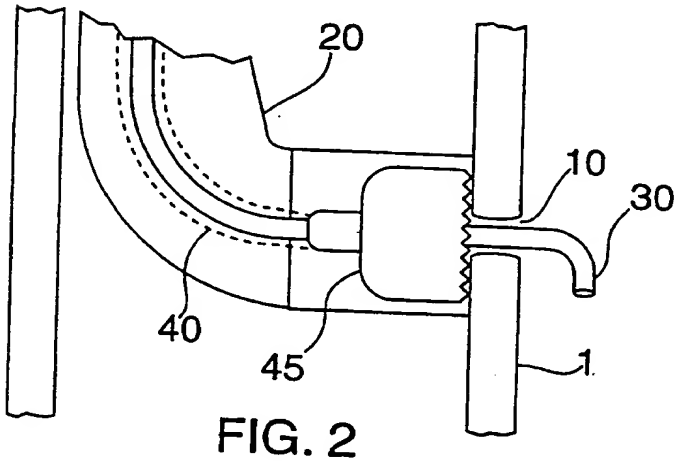


FIG. 2

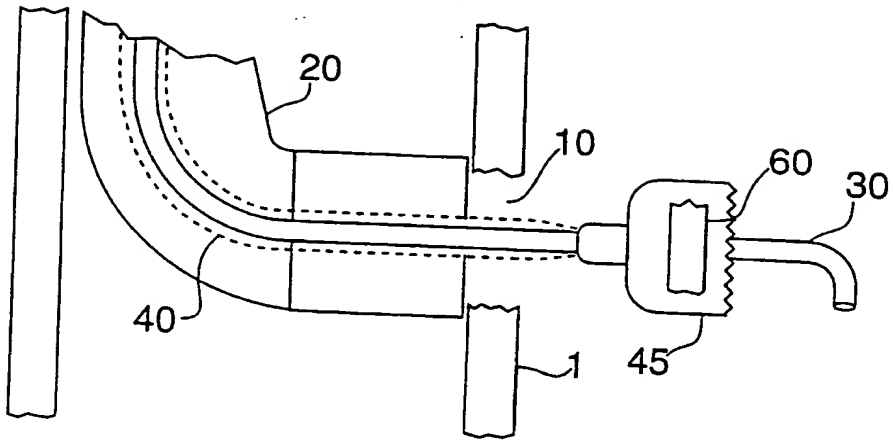


FIG. 3

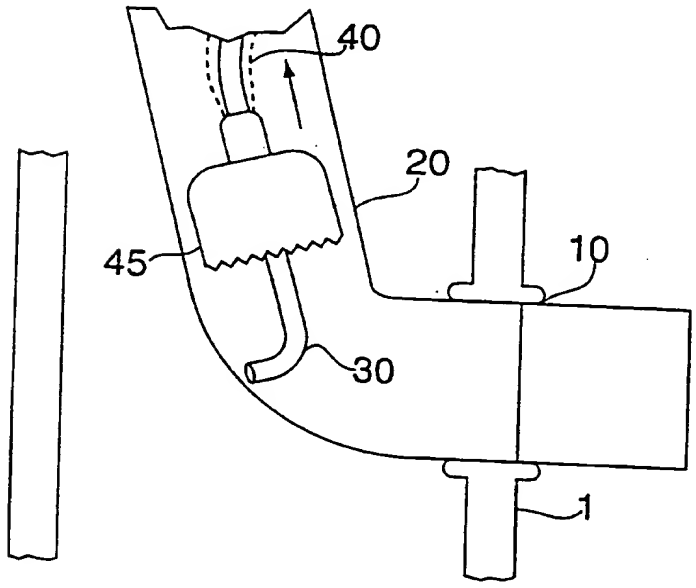


FIG. 4

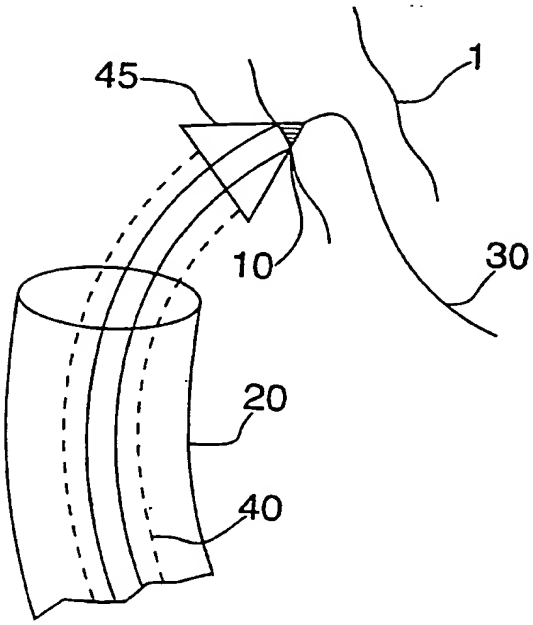


FIG. 5

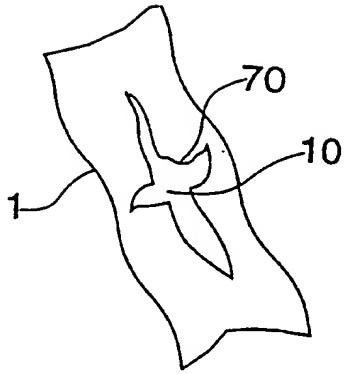


FIG. 6

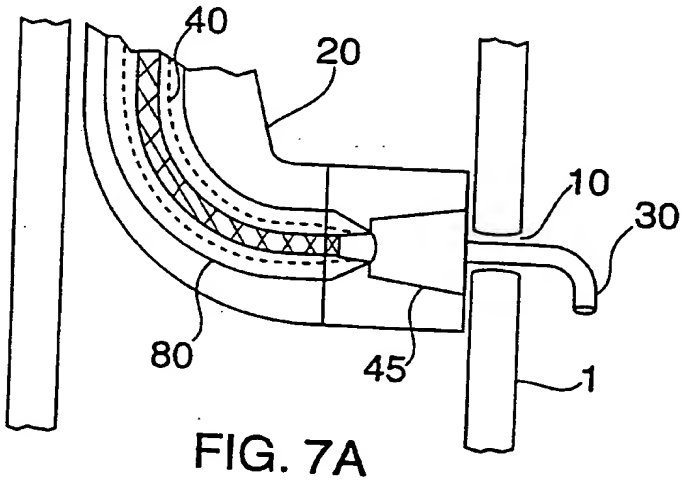


FIG. 7A

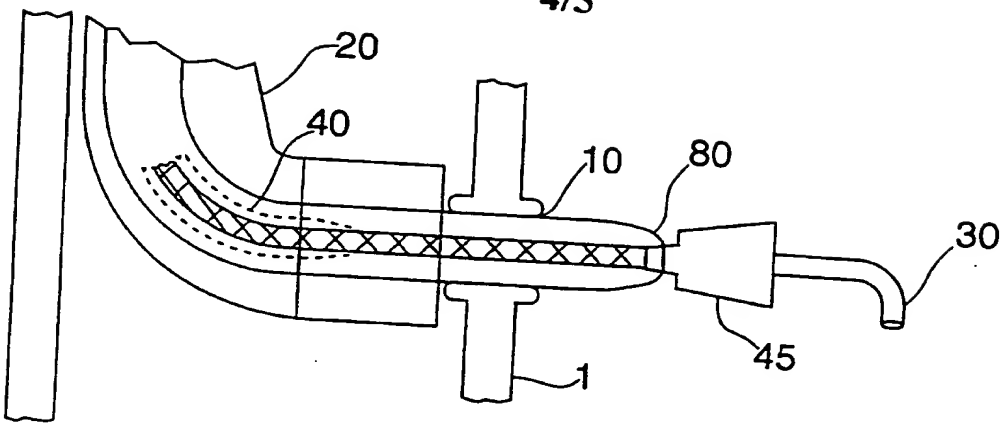


FIG. 7B

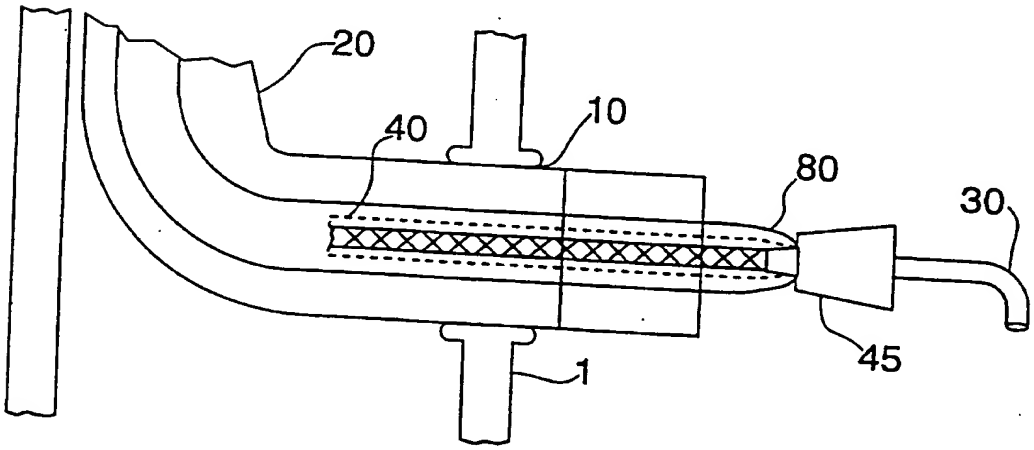


FIG. 7C

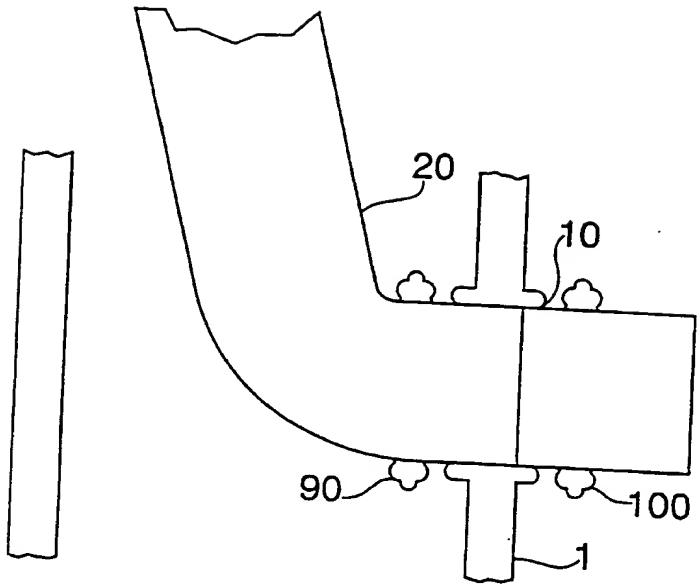


FIG. 8

# INTERNATIONAL SEARCH REPORT

Int. ..ional Application No
PCT/US 99/00102

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/11

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X<br>Y | US 5 702 412 A (POPOV) 30 December 1997<br>see figure 5 | 1,5<br>2-4,7,<br>10-12 |
| Y<br>A | WO 97 13463 A (TRANSVASCULAR)<br>17 April 1997<br>see figures 7,8 | 2-4,7,<br>10-12<br>13 |
| A | US 5 676 670 A (KIM) 14 October 1997<br>see figures 9,10,14,15 | 8,9,13 |
| A | EP 0 807 412 A (USSC) 19 November 1997<br>see figure 8 | 6 |

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 29 March 1999 | 13/04/1999 |

| Name and mailing address of the ISA | Authorized officer |
|---|---|
| European Patent Office, P.B. 5818 Patentlaan 2<br>NL - 2280 HV Rijswijk<br>Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,<br>Fax: (+31-70) 340-3016 | Barton, S |

Form PCT/ISA/210 (second sheet) (July 1992)

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 99/00102

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 23-26
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 99/00102

| Patent document cited in search report | | Publication date | Patent family member(s) | | Publication date |
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